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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,872	09/29/2005	Tatsuo Hoshino	21407 US C038435/0185010	2413
7590 05/08/2006			EXAMINER	
Stephen M Haracz Bryan Cave 1290 Avenue of the Americas New York, NY 10104			CHOWDHURY, IQBAL HOSSAIN	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,872	<b>Applicant(s)</b> HOSHINO ET AL.	
	<b>Examiner</b> Iqbal Chowdhury, Ph.D.	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application is a 371 of PCT/EP03/10573.

Claims 1 - 26 are pending.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group, I claim(s) 1-11, drawn to isolated polynucleotide encoding squalene synthase, vector, host cell and process for producing squalene synthase.

Group, II claim(s) 12, drawn to an isolated polypeptide squalene synthase.

Group, III claim(s) 13, drawn to an antibody of squalene synthase.

Group, IV claim(s) 14-22, drawn to isolated antisense polynucleotide of squalene synthase, vector, and recombinant host cell.

Group, V claims 23-26, drawn to a process for producing carotenoid.

For each inventions I-V above, restriction is also required under 35 U.S.C. 121 and 372.

For each of inventions of Groups I - V above, election is required under 35 U.S.C. 121 and 372.

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2. The inventions listed as Groups I - V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The polypeptide squalene synthase of Group II, polynucleotide encoding a polypeptide squalene synthase of Group I, antisense polynucleotide of squalene synthase of Group IV and an antibody Group III are each unrelated and chemically distinct entities. The only shared technical feature of these groups is that they all relate to a polypeptide squalene synthase. However, this shared technical feature is not a "special technical feature" as defined by PCT Rule 13.2 as it does not define a contribution over the art. Corran et al. ("Squalene synthase in plant pathogenic fungi", GenBank Accession No. X99718, created, 9/15/1996), disclose a DNA encoding a squalene synthase. Thus, a DNA encoding a squalene synthase protein does not make contribution over the prior art.

3. The antibody of Group III does not share any "special technical feature" with Group I and antisense of Group IV as the polynucleotides of Group I and IV are neither made nor used by the antibody of Groups III.

4. A process for producing carotenoids of Group V does not share any "special technical feature" with Group III as the antibody of Group III is neither made nor used by the method of producing carotenoids of Group V.

5. A process for producing carotenoids of Group V does not share any "special technical feature" with Group III as the polynucleotides of Group I are neither made nor used by the method of producing carotenoids of Group V.

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6. A process for producing carotenoids of Group V does not share any “special technical feature” with Group IV as the antisense polynucleotides of Group IV are neither made nor used by the method of producing carotenoids of Group V.

37 CFR 1.475 does not provide for multiple products and/or methods within a single application. Therefore, inventions of Group I - V lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

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requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Iqbal Chowdhury, PhD, Patent Examiner  
Art Unit 1652 (Recombinant Enzymes)

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US Patent and Trademark Office  
Rm. REM 2B69, Mail Box. 2C70  
Ph. (571)-272-8137, Fax. (571)-273-8137  
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A handwritten signature in black ink, appearing to read 'P. Achutamurthy', written in a cursive style.

**PONNATHAPU ACHUTAMURTHY**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1300**